K030264

FEB 2 6 2003

Special 510(k): Device Modification: Quadrox Safeline HMO 2030

510(k) SUMMARY

SUBMITTER:	Jostra AG, Hechinger Strasse 38 72145 Hirrlingen, Germany
CONTACT PERSON:	Katrin Schwenkglenks Phone: +49 (7478) 921-151 Fax: + 49 (7478) 921-400
DATE PREPARED:	January 24, 2003
DEVICE TRADE NAME:	Jostra Hollow Fiber Membrane Oxygenator Quadrox Safeline
COMMON/USAUAL NAME	Hollow Fiber Membrane Blood Oxygenator with Integral Heat Exchanger
CLASSIFICATION NAME	Cardiopulmonary Bypass Oxygenator Cardiopulmonary Bypass Heat Exchanger
PREDICATE DEVICE OR LEGALLY MARKETED DEVICE:	Jostra Hollow Fiber Membrane Oxygenator Quadrox Safeline HMO 1030

DEVICE DESCRIPTION/INDICATONS FOR USE

The Hollow Fiber Membrane Oxygenator Quadrox Safeline is intended for use in an extracorporeal perfusion circuit to oxygenate blood and remove carbon dioxide and to temper blood during short duration cardiopulmonary bypass procedures lasting 6 hours or less.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The Jostra Hollow Fiber Oxygenator Quadrox Safeline HMO 2030 is identical to the Jostra Hollow Fiber Oxygenator Safeline Quadrox HMO 1030 in design, intended use, method of operation, components, packaging, and fundamental scientific technology. The primary difference between the two devices is that the Jostra Hollow Fiber Oxygenator Quadrox Safeline HMO 2030 contains a heat exchanger fiber made of polyurethane (instead of polyethylene) which reduces the risk of electrostatic discharge for the patient significantly.

TESTING TO DETERMINE SUBSTANTIAL EQUIVALENCE

In-vitro tests were performed to demonstrate that the Jostra Hollow Fiber Oxygenator Quadrox Safeline HMO 2030 described in this submission is substantially equivalent to the Jostra Hollow Fiber Oxygenator Safeline Quadrox HMO 1030 (K992559).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2003

Jostra AG
Ms. Katrin Schwenkglenks
Regulatory Affairs
Hechinger Strasse 38
72145 Hirrlingen, Germany

Re: K030264
Trade/Device Name: Quadrox Safeline Hollow Fiber Membrane Oxygenator HMO 2030
Regulation Number: 21 CFR 870.4350
Regulation Name: CARDIOPULMONARY BYPASS OXYGENATOR
Regulatory Class: Class II
Product Code: DTZ
Dated: January 24, 2003
Received: January 27, 2003

Dear Ms. Schwenkglenks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030264

Device Name: Jostra Safeline Quadrox Hollow Fiber Membrane Oxygenator

Indications for Use

The Hollow Fiber Membrane Oxygenator Quadrox Safeline is intended for use in an extracorporeal perfusion circuit to oxygenate blood and remove carbondioxide during short duration cardiopulmonary bypass procedures lasting 6 hours or less.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use Only

(Division Sign-Off)
Division of Cardiovascular Devices

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